

Anita F. McMahon
1646 Belmont Avenue
Baton Rouge, LA 70808

May 11, 1999

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Dockets Management Branch (HRA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

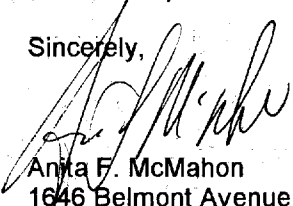
I have the medication I need because a compounding pharmacy in Wisconsin went to the trouble to develop the medication when standard pharmacies and doctors were unwilling to provide it. In fact I was laughed at by some physicians when I complained that the AMA approved course of medication was causing me difficulty! My family care physician keeps trying to get local pharmacies to provide this medication and they have been unwilling and unable over the last several years.

Under the proposed changes contained in the Memorandum of Understanding (MOU) as published on January 21 of this year - as well as the Compounding Section 503A of the Modernization Act - I could no longer obtain this medication. This is certainly not in my best interest and can not be anyone else's best interest who is dependent on the creative solutions the compounding pharmacies are providing in the current vacuum generated by the standard medical establishment.

In all the years I have been taking these drugs, my Compounding Pharmacy has gone out of their way to answer all my questions and to talk to my primary care physician at any time about their compounds. At no time did I feel that what I was taking was unsafe. Therefore I can only conclude that the proposed actions of the FDA under this MOA would not be as a watch dog for my safety but would, instead, limit my accessibility to medication that is right for me.

This MOU must be amended to eliminate any restriction to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel.

Sincerely,



Anita F. McMahon
1646 Belmont Avenue
Baton Rouge, LA 70808

cc: Sen. John Breaux
Sen. Mary Landreu
Rep. Richard Baker
Dr. Linda Stewart
Women's International Pharmacy

98N-1265

C2154

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5630 FISHERS LANE, Room 1061
Rockville MD 20857
Document Mgt. Div. 827-4573³⁰¹

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